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10/724,870	12/02/2003	Randall S. Hickle	82021-0033	1625

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HOGAN & HARTSON LLP
IP GROUP, COLUMBIA SQUARE
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004

EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
03/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcptopatent@hhlaw.com
rogruwell@hhlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/724,870	HICKLE, RANDALL S.	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. According to the Amendment, filed 04 December 2009, the status of the claims is as follows:

Claim 32 is currently amended;

Claims 2-7, 9-12, and 14 are as originally filed;

Claims 1, 8, 13, and 15 are previously presented; and

Claims 16-31 are cancelled.

2. The 35 U.S.C. 112, second paragraph, rejections to claim 32 is WITHDRAWN in view of the Amendment, filed 04 December 2009.

Response to Arguments

3. Applicant's arguments, see Remarks, p. 5, filed 04 December 2009, with respect to the rejection of claims 1-15 and 32 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, have been fully considered, and are persuasive. The rejection of claims 1-15 and 32 has been withdrawn.

4. Applicant's arguments, see Remarks, pp. 5-7, filed 04 December 2009, with respect to the rejection of claims 1-15 and 32 under 35 U.S.C. 103(a) as being unpatentable over Schnitzer et al, U.S. Patent No. 5,692,497 A ("Schnitzer"), in view of Derrick et al, U.S. Patent No. 5,046,491 A ("Derrick"), and further in view of Allen et al,

U.S. Patent No. 6,142,950 A ("Allen"), have been fully considered, but they are not persuasive.

Applicant contends, see Remarks, p. 6, the following:

> Schnitzer fails to disclose an electronic controller that automatically gathers information regarding an additional aspect of the respiratory condition of the patient when the system alerts the user of a potential problem. Schnitzer discloses "continuous capture of patient data for 'real-time' read out or storage for future...use" and warning buzzers, alarms or lights, but Schnitzer does not teach or suggest an electronic controller that gathers information regarding an additional aspect of the respiratory condition, as in claim 1. The monitoring of Schnitzer may disclose continuing to gather the same type of information that was gathered prior to an alarm situation, but Schnitzer does not disclose also gathering new types of information when alerting the user.
>
> The Office Action points to Schnitzer's disclosure of calculating V_D/V_T, CO_2 production, or O_2 consumption. However, this calculation is not information *gathering*, but rather manipulation of/calculations based on previously gathered data (or in real-time, currently gathered data regarding the same aspect of the respiratory condition). Further, the CPU of Schnitzer is not *automatically* gathering this information; these calculations are "operator-specific." Schnitzer does not teach or suggest an electronic controller that *automatically gathers information regarding an additional aspect of the respiratory condition of the patient* when said visual display alerts the user.

However, this argument is not persuasive. Based on broadest reasonable interpretation, Schnitzer teaches the limitation "said electronic controller automatically gathers information regarding an additional aspect of the respiratory condition of the patient when said visual display alerts the user" in claim 1. "Gather" is defined as "to bring together or assemble from various places, sources, or people; collect gradually" or "to collect", according to *Dictionary.com Unabridged*. Random House, Inc. 19 Mar. 2010. <Dictionary.com http://dictionary.reference.com/browse/gather>. Thus, based on broadest reasonable interpretation, "gathering information regarding an additional

aspect of the respiratory condition..." includes information collected from a calculated source. Schnitzer explicitly states "[t]he information collected and controlled by the system 10 is both viewed and defined at the display and interface section 90."

In addition, Schnitzer discloses the following:

> With further reference to FIG. 2, on-line visual color display and interface 132 is provided for the user to monitor and control all activities associated with the subsystem 136. The feedback circuitry of the subsystem 136 with the microprocessor thus permits closed-loop control of rate, flow, oxygen concentration, circuit PEEP levels, and concentrations and flows of any other gases. These parameters are derived from the signals produced by the various sensors of FIG. 3. In the illustrated form of the invention, these signals are sampled, via the A-D converter 134, and stored in memory 135 at user-defined rates for as-needed retrieval and analysis. The memory 135 may be, for example, a floppy disk drive or internal RAM or hard drive of an associated computer. These patient data may be stored to provide a permanent log of all events related to the patient's course on the ventilator, and allow on-line and retrospective analysis of pulmonary function, i.e., compliance, and gas analysis as a function of time. Furthermore, the CPU 130 can perform operator-specific physiological calculations on-line and in real-time, such as the calculation of V.sub.D /V.sub.T, CO.sub.2 production, and O.sub.2 consumption. Alternatively, these data can be stored for later analysis and review.

The above disclosure teaches how the information regarding rate, flow, oxygen concentration, and PEEP levels is *automatically gathered*, or independently collected, and stored within the memory of an electronic controller, i.e. associated computer. According the above disclosure, CPU 130 collects or calculates information regarding an aspect of respiratory condition independent of human assistance in the collection or calculation of the information.

For the above reasons, the 35 U.S.C. 103(a) rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnitzer in view of Derrick, and further in view of Allen.

Claims 1-15: Schnitzer teaches a respiratory monitoring system 10 comprising: a patient interface (see schematic in fig. 2) comprising a "patient insert" (i.e. endotracheal tube, ETT, or reverse thrust catheter, RTC, see col. 7, ll. 35-37) 12 and a visual display 132, the nasal cannula 12 comprising at least a first nasal capnography port 19 and a first pressure sensor port 64 (see fig. 1B); a respiratory monitor (flow/pressure bi-direct alert, which detects an incorrect flow and/or an undesirable pressure) 18, comprising a pressure sensor; and an electronic controller (central processor or microprocessor 130) 22; wherein the electronic controller manages a drug delivery device, such as a sedation and analgesia system (see col. 2, ll. 29-35, and col. 4, ll. 34-40); user interface allowing a user to enter inputs corresponding to thresholds relating to inhalation or exhalation of the patient (see col. 8, ll. 54-59; wherein pressure waveform analysis and segmentation is used to identify one of respiratory effort and effect (see col. 8, ll. 49-67); wherein alarm conditions are determined based certain criteria including relation to predetermined thresholds (see col. 9, ll. 25-36); LEDs (see col. 3, ll. 52-59); wherein the visual display 132 is updated in real time (see col. 4, ll. 24-34).

In addition, Schnitzer teach the visual display 132 alerts the user of a potential problem and the electronic controller 22 automatically gathers information regarding an additional aspect of the respiratory condition of the patient, e.g. one of whether the patient is inhaling or exhaling, the rate of inhalation and/or exhalation, and the

magnitude of inhalation and/or exhalation, when said visual display alerts the user as follows (see col. 4, ll. 128-34):

> The computer or microprocessor control of the invention provides flexibility so far unavailable in existing ventilators, so as to provide, for example, continuous capture of patient data for "real-time" read out or storage for future clinical or research use. The invention also provides for continuous and "real time" monitoring of relevant patient data, e.g., physiological trends, compositions, flows, pressures, volumes, and dynamic compliance data; and responds or notifies the user or connected facility of user-selected warnings, e.g., a warning buzzer, alarm or light, when a selected data characteristic is met.

In addition, Schnitzer teaches the following (see col. 8, ll. 49-67):

> The feedback circuitry of the subsystem 136 with the microprocessor thus permits closed-loop control of rate, flow, oxygen concentration, circuit PEEP levels, and concentrations and flows of any other gases. These parameters are derived from the signals produced by the various sensors of FIG. 3. In the illustrated form of the invention, these signals are sampled, via the A-D converter 134, and stored in memory 135 at user-defined rates for as-needed retrieval and analysis. The memory 135 may be, for example, a floppy disk drive or internal RAM or hard drive of an associated computer. These patient data may be stored to provide a permanent log of all events related to the patient's course on the ventilator, and allow on-line and retrospective analysis of pulmonary function, i.e., compliance, and gas analysis as a function of time. Furthermore, the CPU 130 can perform operator-specific physiological calculations on-line and in real-time, such as the calculation of V_D/V_T, CO_2 production, and O_2 consumption. Alternatively, these data can be stored for later analysis and review.

Thus, Schnitzer's electronic controller 22 can gather information regarding an additional aspect of the respiratory condition, e.g. V_D/V_T, CO_2 production, or O_2 consumption, through "operator-specific physiological calculations on-line and in real-time".

Although Schnitzer does not explicitly teach a nasal cannula, an ear mount and a support band, Schnitzer teaches that the "subsystem 136 is connected for fluid communication with the patient 138, for example, through pneumatic tube (e.g., an ETT)

and an RTC (not shown)" (see col. 7, ll. 35-37). However, Derrick teaches an apparatus for gas analysis comprising a nasal cannula 10, an ear mount/support band 28 that is adapted for placement on both ears and provides stability (see figs. 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schnitzer to have a nasal cannula assembly because the scope of Schnitzer's invention encompasses other types of fluid communication with patients other than ETT and RTC, such as nasal cannula.

Neither Schnitzer nor Derrick teaches a visual display that "is adapted to be positioned at a suitable location on the body of a patient such that said indicators are visible to a user while simultaneously observing the patient". However, this display feature is well-known in the art. For example, Allen teaches a respiratory monitoring system (apnea screening device) 10 comprising: a nasal interface/cannula (airflow sensor) 11 with an ear mount (adjustable elastic strap worn around the back of the head and around the ears for good stability and comfort) 20; and a display (display means) 16 (see col. 5, ll. 6-24, and col. 6, ll. 26-38). Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Schnitzer in view of Derrick to have a respiratory monitoring system with a visual display adapted to be positioned at a suitable location on the body of a patient as taught by Allen in order to have a display attached to a patient that is unobtrusive, comfortable, and stable (as stated by Allen, see col. 6, ll. 26-38).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The other patents cited in the PTO-892 teach subject matter related to the Applicant's claims. The Examiner suggests reviewing these patents before responding to the present Office Action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/N. N./
Examiner, Art Unit 3735
03/19/2010